Attachment 2 9 Sep 2011 revised section for K112131

5.0 510(k) Summary

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SEP 29 2011

Submitters Name and Address
Neodyne Biosciences, Inc.
127 Independence Drive
Menlo Park CA 94025

Contact Person
Peggy McLaughlin
Consulting Vice President, Clinical & Regulatory Affairs
Neodyne Biosciences, Inc.
127 Independence Drive
Menlo Park CA 94025
Telephone: 650 504-8501
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Date Prepared
25 July 2011

Name of Medical Device
Device Classification Name: Silicone Sheeting
Device Classification Number: 21 CFR 878.4025
Device Class: Class 1
Proprietary Name: Neodyne Dressing

Predicate Devices
Biodermis Corporation Epi-Derm Silicone Sheeting (K003948)
3M Company Steri-Strip Antimicrobial Skin Closures (K813265)

Intended Use

The Neodyne Dressing is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.

Device Description
The Neodyne Dressing is a non-sterile, single use adhesive silicone sheet to be used to protect and manage a newly formed, closed scar. The Dressing is pre-strained prior to application and applied over the new scar. The silicone sheeting protects and stress shields the scar.

Safety and Performance

Results of safety and performance testing demonstrate that the Neodyne Dressing is substantially equivalent to the predicate devices. The performance of the Neodyne Dressing is due to both its materials (silicone sheeting) and the stress shielding provided by the pre-strained dressing. Bench testing confirmed that the Neodyne Dressing provided the intended strain relief and functioned as intended.

Substantial Equivalence

The Neodyne Dressing is as safe and effective as Steri-Strips and Epi-Derm Silicone Sheeting. The Neodyne Dressing has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Neodyne Dressing and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Neodyne Dressing functions as intended. Thus, based on the indications for use, technological characteristics, and performance data, the Neodyne Dressing has been shown to be substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

Neodyne Biosciences, Inc.
% Ms. Peggy McLaughlin
Consulting VP, Clinical & Regulatory Affairs
127 Independence Drive
Menlo Park, California 94025

SEP 29 2011

Re: K112131
Trade/Device Name: Neodyne Dressing
Regulation Number: 21 CFR 878.4025
Regulation Name: Silicone sheeting
Regulatory Class: I
Product Code: MDA
Dated: September 9, 2011
Received: September 13, 2011

Dear Ms. McLaughlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1 9 Sep 2011 revised section for K112131

4.0 Indications for Use Statement

Indications for Use Form

510(k) Number: K112131

Device Name: Neodyne Dressing

Indications for Use:

The Neodyne Dressing is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Kraus for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112131